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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,274	01/28/2004	Hong Luo	200PP370A	3419

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LEGAL DEPARTMENT
NOVEON, INC.
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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/766,274

Applicant(s)

LUO ET AL.

Examiner

Frederick Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 18, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Previous Rejections

Unless specifically maintained infra, all previous rejections are withdrawn.

Obviousness Rejections (New)

1) Claims 1-3 and 9-11 are rejected under 35 USC 103(a) as being unpatentable over Rennie (USP 5,368,843) in view of Nakashima et al (USP 4,259,316).

Applicant contends that the examiner has mischaracterized Rennie insofar as silica and alumina are inert materials which could not be cations. (Remarks, page 8, paragraph 2). The claims prior to amendment required, however, multivalent cation "containing" agents. This is merely a statement of future intended use; alumina "contains" cations which can be released under the proper conditions (as outlined by applicant's own analysis regarding pH in the Remarks). Moreover, silica and alumina abrasives, unless stringently purified, contain various impurities which, where not multivalent cations per se, are capable of providing cations under appropriate conditions. Accordingly, the examiner stands by his original position.

Applicant is correct, however, insofar as Rennie no longer reads on the instant claims as currently amended. Stated alternatively, Rennie now differs from the instant claims insofar as it does not disclose a multivalent cation per se. Accordingly, a new ground of rejection is required and is set forth herein.

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The secondary reference teaches that xanthan and guar gums are known thickeners for toothpaste compositions, and abrasives useful therewith include calcium pyrophosphate (one of applicant's preferred species as required by instant claims 8 and 16), silica, and alumina, among others. See column 4, lines 20-27. The compositions also contain the anticaries agent stannous fluoride (stannous ions being multivalent cations), which is also more effective than other fluorides in providing acid resistance (column 1, lines 30-34; see also column 3, lines 12-30). Working example 5 (column 10) exemplifies a composition containing calcium pyrophosphate, guar gum, and stannous fluoride.

The secondary reference thus differs from the instant claims insofar as it does not specifically disclose a crosslinked polyacrylic acid.

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. See Sinclair & Carroll Co. v. Interchemical Corp., 325 US 327, 65 USPQ 297 (1945); see also In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Accordingly, it would have been obvious to have selected calcium pyrophosphate as an abrasive in the primary reference toothpastes, motivated by the understanding that it is a conventional toothpaste abrasive as taught by the secondary reference, consistent with the reasoning of the cited precedent. The same reasoning applies to the use of guar gum as a thickening agent as well as stannous fluoride as an anticaries agent (additional motivation to use the latter would also reside in the desire to provide the improved acid resistance imparted thereby, as taught by the secondary reference).

In responding to the previous rejection, Applicant argues:

While the Rennie citation discloses that several of the disclosed embodiments of the invention may contain a synergistic combination of a gum and an acrylic acid polymer, it

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must be pointed out that the general teaching of the combination of a generic gum and an acrylic acid polymer does not extend to toothpaste compositions. Rennie takes great measure to distinguish the disclosed toothpaste composition for the other disclosed embodiments of in the citation. At column 6, lines 13-23, Rennie is very specific in as to the type of gum that is intended for toothpaste compositions in that Rennie states:

“In this respect, it has surprising been found that the inclusion of the synergistic mixture in toothpastes can provide toothpastes which have a higher gloss, a cleaner ribbon break and a smoother texture than toothpastes which have been thickened with the aid of current thickeners, e.g., sodium carboxymethylcellulose. The present invention thus beneficially extends to a liquid system in the form of toothpaste containing 0.25 to 5 wt. % of thickening mixture comprising preferably, with respect to the final composition, 0.2 to 3 wt. % synthetic cross-linked polymer 0.05 to 2 wt % xanthan gum and/or xanthan gum derivative.” (Remarks, pages 6 and 7; emphasis added).

In view of this, applicant concludes, the “disclosed gum is specific to xanthan gum and/or xanthan gum derivatives”, such that there “is no teaching, suggestion, or implication drawing any equivalence between xanthan gum and guar gum for used in stabilizing toothpaste compositions.” (Remarks, page 7, second paragraph). Given the multitude of choices involved, applicant contends, the examiner is applying an improper “obviousness to try” standard. (Remarks, page 9, paragraphs 3 and 4; see also page 10, paragraph 1.

The examiner does not agree with this interpretation of the primary reference. In the passage at column 6, lines 13-23, patentee merely prefers the use of xanthan gums; it does not state that other gums are not useful. What it does positively state, however, is that gums are preferred to carboxymethylcellulose. This is consistent with the disclosure at column 10, lines 31-34, stating that the toothpaste compositions disclosed in working example 6 “were glossier and smoother than a commercially available toothpaste thickened with a Carbopol/sodium carboxymethyl cellulose mixture” (emphasis added) – and not a toothpaste thickened with a different gum. (Note also that the reference clearly states at column 1, lines 58 and 59 that the “present invention is particularly concerned with the above gum-type thickening agents”, which includes both xanthan and guar

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gums). This would in fact seem to be a teaching directing one to select gums over carboxymethylcellulose, both of which are disclosed by the secondary reference, in formulating toothpaste compositions.

As evidence that xanthan gum is not equivalent to a galactomannan gum, applicants have presented a table of experimental results that were obtained at the time of the invention but not included in the instant specification. Experiment 1 purportedly demonstrates that xanthan gum does not stabilize compositions against multivalent cations.

This evidence is not persuasive. First, since the data is not presented in the form of a Rule 132 affidavit, it represents (at this time) nothing more than unsubstantiated attorney argument. Furthermore, assuming *arguendo* the validity of the showing, the instant claims are not commensurate in scope therewith. The only cation source used in the comparison is calcium carbonate, a very poorly water soluble compound which would provide a correspondingly low amount of calcium; the showing does not support reasonably support a finding of unexpected results for cations generally (particularly from fully soluble compounds such as stannous fluoride).

2) Claims 8 and 16 are rejected under 35 USC 103(a) as being unpatentable over Rennie (USP 5,368,843) in view of Nakashima et al (USP 4,259,316), the combination being taken further in view of Lynch et al (USP 4,855,128).

The primary and secondary references, and the reason for combining their teachings, is provided supra. The motivation for further applying the teachings of the

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tertiary reference thereto remains substantially the same as that provided in the corresponding rejection at pages 5 and 6 of the previous Office action.

3) Claims 4-7 and 12-15 are rejected under 35 USC 103(a) as being unpatentable over Rennie (USP 5,368,843) in view of Nakashima et al (USP 4,259,316), the combination being taken further in view of Lynch et al (USP 4,855,128), and further in view of Brown et al (USP 2,798,053).

The primary and secondary references, and the reason for combining their teachings is provided supra. The motivation for further applying the teachings of Lynch et al and Brown et al thereto remains substantially the same as that provided in the corresponding rejection at pages 5 and 6 of the previous Office action.

Action is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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